IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, and WARNER-LAMBERT COMPANY LLC,	
Plaintiffs,	Civil Action No. 1:08-07231
v.	Consolidated with Civil Action No. 1:09-cv-6053
APOTEX INC. and APOTEX CORP.,	Judge Robert M. Dow Jr.
Defendants.	Magistrate Judge Martin C. Ashman

DEFENDANT APOTEX'S BRIEF IN OPPOSITION TO PLAINTIFF PFIZER'S MOTION TO DENY APOTEX'S MOTIONS FOR SUMMARY JUDGEMENT OR, ALTERNATIVELY, TO STAY BRIEFING [DKT. ITEM NO. 216]

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Apotex respectfully opposes Plaintiff Pfizer's Motion to Deny Apotex's Motions for Summary Judgment Without Prejudice to Renew, or in the Alternative Stay Briefing of those Motions, Until After the Completion of Fact and Expert Discovery and Issuance of a Claim Construction Order (D.I. 216) ("Pfizer's Motion")[1] as follows.

I. INTRODUCTION.

On August 6, 2010, after enduring years of delay and baseless motion practice by Pfizer, Apotex filed two motions for summary judgment of non-infringement: one on U.S. Patent Nos. 5,686,104 ("'104 patent") and 6,126,971 ("'971 patent") (D.I. 176), and the other on U.S. patent No. 5,969,156 ("'156 patent") (D.I. 182). Apotex did so because that is the only way it can clear up the generic bottleneck that Pfizer has created and secure approval of its competing generic drug. True to form, rather than respond on the merits (because it realistically can't), Pfizer again attempts to throw up yet more roadblocks to avoid resolution of this case—all in a transparent attempt to delay lawful generic competition. The Court should deny Pfizer's baseless motion for what it is, and allow this case to proceed on the merits.

Pfizer moves, in the first instance, "to deny" Apotex's motions without prejudice to renew after completion of fact discovery and *Markman* proceedings. But the Court has already rejected this very request from Pfizer, initially raised at the August 17, 2010 hearing—absolutely nothing has changed since then to warrant a different result now.

Pfizer next seeks to stay briefing, arguing that it needs discovery for claim construction and on infringement. But claim construction is a purely legal issue for the Court to decide with recourse to *intrinsic* evidence (the claims, specification, and prosecution history) and, when necessary, dictionaries and treatises. No "discovery" is required, and Pfizer has not shown

[1] Pfizer's opening brief in support of its Motion (D.I. 217) shall be referred to herein as "Pfizer's brief" or "Plaintiffs' brief."

otherwise. Pfizer also neglects to mention that the parties expressly agreed to forego separate *Markman* proceedings in favor of resolving any disputes during dispositive motions—a perfectly lawful practice and precisely what Apotex seeks to do here. Indeed, to the extent there even are any disputes on claim construction, courts routinely resolve them via summary judgment, because such legal disputes cannot create a genuine issue for trial. Pfizer shouldn't be heard to argue otherwise now, just because it doesn't want Apotex's motions decided, ever. As to the merits, Pfizer has already conceded non-infringement of the '104 and '971 patents in a unilateral covenant-not-to-sue, and so no discovery or claim construction is required. And on the '156 patent, Apotex's ANDA (and the DMF it references) contain all of the information necessary to resolve the motion. The bottom line is that there is no legitimate reason to delay adjudication of Apotex's motions.

Last, Pfizer attempt to circumvent the express requirements of FED. R. CIV. P. 56(f) is equally baseless. To justify discovery, Pfizer must substantiate its claims with a particularized showing and affidavit under Rule 56(f). *Intellect Wireless, Inc. v. T-Mobile USA, Inc.*, No. 08 C 1215, 2010 WL 3257924, at *2 (N.D. Ill. Aug. 13, 2010). That Pfizer intentionally failed to do so speaks volumes about its baseless motion, and is reason enough to deny it.

II. FACTUAL BACKGROUND.

On June 30, 2010, this Court denied Pfizer's first motions to dismiss, and set forth the relevant facts. *Pfizer Inc. v. Apotex Inc.*, No. 08-cv-7231, 09-cv-6053, 2010 WL 2649841, at *1-4 (N.D. Ill. Jun. 30, 2010) ("June 30 Order"). We respectfully incorporate those facts herein.

A. Facts Post-June 30, 2010.

Shortly thereafter, and true to form, Pfizer engaged in a flurry of baseless activity designed to further delay resolution of this action and Apotex's Counterclaim Counts, including a motion to reconsider the Court's June 30 Order (D.I. 155). Pfizer followed that by issuing a

unilateral covenant-not-to-sue for the '104 and '971 patents, and filing a so-called "Counter-Counterclaim" asserting a claim for infringement of the '156 patent (D.I. 160). Incredibly, Pfizer then filed a second motion to dismiss Apotex's counterclaims directed to the '104 and '971 patents, under the absurd theory that asserting the '156 patent somehow eliminated jurisdiction over the other patents (D.I. 161). Because of Pfizer's unending cascade of baseless motions designed to delay any timely resolution of this action, Apotex had no choice but to move for summary judgment of non-infringement of the '104 and '156 (D.I. 176) and '971 patents (D.I. 182). Only by securing such judgments can Apotex secure approval of its competing generic drug—precisely what Pfizer seeks to prevent.

B. The August 17, 2010 Presentment Date for Apotex's Summary Judgment Motions and the Instant Motion.

At the August 17, 2010 presentment date for Apotex's summary judgment motions, Pfizer expressly requested that the Court deny Apotex's summary judgment motions outright as premature:

> MS. BOURKE: We would recommend that at this time the court deny the summary judgment motions without prejudice and give them leave to renew after we have completed discovery and we go in front of the magistrate judge and try and get a discovery schedule set, which hasn't been done yet.

(D.I. 217-3, Pls.' br. Ex. C, Aug. 17, 2010 Tr. of Proceedings before the Hon. Robert M. Dow, Jr. ("Aug. 17 Tr.") 4:11-15). This Court expressly rejected Pfizer's request:

> MR. ALUL: . . . And so we feel that your Honor got it right on June 30th, that there does exist subject matter jurisdiction over Apotex's counterclaims, and that Apotex's counterclaims should proceed and that your Honor -- and that Apotex should be allowed to file summary judgment motions and your Honor should rule on them.
>
> THE COURT: well, you have already filed them, so I can't stop you from filing them ***nor would I want to***.

(D.I. 217-3, Pls.' br. Ex. C, Aug. 17 Tr. 7:15-22 (emphasis added)). Moreover, the Court indicated that it was inclined to set a briefing schedule for Apotex's summary judgment motions:

> THE COURT: . . . I'm not averse to setting a briefing schedule here, but I don't -- ***I think it's really going to be a burden on Pfizer to demonstrate that I shouldn't go ahead and let you brief this***. But if you want to file a motion to stay the briefing on the summary judgment motion and explain to me all the things -- I can try the best I can to follow this bouncing ball here . . . .

(*Id*. at 8:6-12 (emphasis added)). Last, the Court instructed Pfizer to include any Rule 56(f) arguments in its motion to stay briefing. (*Id*. at 8:17 – 9:5). This motion followed (D.I. 216).

C. Discovery to Date.

On March 17, 2009, the parties submitted the first of two joint Rule 26(f) reports. (*See* D.I. 50, Joint Rule 26(f) Report). Importantly, the parties did not agree to, nor did the March 2009 report include, a restriction on the early filing of dispositive motions. Furthermore, Section M.3 of the March report stated the following:

> **3. Claim Construction.** The parties propose that ***any claim construction issues be resolved in the dispositive motion context, and that this case be exempted from the requirements set forth in the Court's Standing Order for Claim Construction.***

(*See* D.I. 50, Joint Rule 26(f) Report § M.3. (emphasis added)). On August 28, 2009, the parties submitted a second joint Rule 26(f) report that included the same provision on claim construction and also omitted any restrictions on early filing of dispositive motions. (*See* D.I. 99, Revised Joint Rule 26(f) Report, generally and § P).

Following an October 21, 2009 status, the Court ordered discovery to proceed "focused primarily on [U.S. Patent No. RE 40,667 E] as to which no motion to dismiss is pending or anticipated." (D.I. 109, Oct. 27, 2009 Minute Order 1). Discovery on that patent is proceeding, and any disputes are being hashed out before Magistrate Judge Ashman. *See Pfizer Inc. v. Apotex Inc.*, No. 08 C 7231, 2010 WL 3087458 (N.D. Ill. Aug. 4, 2010).

Following denial of Pfizer's first motion to dismiss, this Court held a status on July 27,

2010. Without notice,[2] Pfizer filed a unilateral status report proposing an entirely different schedule from the prior joint reports. (D.I. 165, Status Report by Pls. Pfizer 4). As Apotex pointed out at the July 27 status, this was both improper and an impractical approach given the changed circumstances. (D.I. 217-2, Pls.' br. Ex. B, July 27 Tr. 3:24 – 4:10). The Court then referred the parties to Judge Ashman to for scheduling (D.I. 217-2, Pls.' br. Ex. B, July 27 Tr. 4:11-22), but the parties have yet to negotiate a comprehensive scheduling order.[3] At a July 27 status, however, the Court allowed discovery to proceed on U.S. Patent No. 5,273,995 ("'995 patent") and the '156 patent. (D.I. 217-2, Pls.' br. at Ex. B, July 27 Tr. 10:14-20).

III. ARGUMENT.

A. This Court Has Already Rejected Pfizer's Request for an Order Denying Apotex's Summary Judgment Motions, And Should Do So Again.

As with everything else in this case, Pfizer wants yet another do-over because it doesn't like the result. This Court already rejected Pfizer's express request for an order denying Apotex's motions. (D.I. 217-3, Pls.' br. Ex. C, Aug. 17 Tr. 7:21-22 ("THE COURT: Well, you have already filed [the summary judgment motions], so I can't stop you from filing them nor would I want to.")). That Pfizer doesn't like that result is not reason to reconsider it. Indeed, Pfizer has provided no legal or practical reason to do so, because there is none.

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[2] Pfizer assertion that it "attempted to discuss setting a schedule for this Action," but that "Apotex declined Pfizer's invitation," is disingenuous and baseless. As Pfizer well knows, given the flurry of activity and yet more baseless motions from Pfizer, Apotex made it clear that it was more prudent to appear before the Court and find out what the Court's preferred course of action was, in view of Pfizer's unending cascade of motions to dismiss. (D.I. 217-2, Pls.' br. Ex. B, July 27, 2010 Tr. of Proceedings before the Hon. Robert M. Dow, Jr. ("July 27 Tr.") 3:7 – 4:3).

[3] Pfizer's suggestion that Apotex somehow "[a]voids [a]greement on a [s]chedule" is not only untrue, but borders on bad faith. (*See, e.g.*, D.I. 217, Pls.' br. 4). Apotex has negotiated two separate schedules with Pfizer. (*See* D.I. 50 and 99). But Pfizer itself ***has opposed*** entering either one because of its continuing objections to subject matter jurisdiction. (D.I. 50, Joint Rule 26(f) Report 3; D.I. Revised Joint Rule 26(f) Report 7).

B. Pfizer's Unending Subject Matter Jurisdiction Games Should Not Hold Up Briefing on Apotex's Summary Judgment Motions.

In its June 30 Order, this Court correctly found subject matter jurisdiction for Apotex's counterclaims on the '104, '156, and '971 patents. *Pfizer*, 2010 WL 2649841, at *16. But Pfizer, once again, doesn't like that result (correct as it may be), and so is doing everything in its power to destroy subject matter jurisdiction and delay adjudication of Apotex's Counterclaim, making timely approval of Apotex's ANDA impossible. Pfizer's shenanigans are tiresome and should not be countenanced. But even more importantly, such gamesmanship should not hold up briefing on Apotex's summary judgment motions. As Apotex has repeatedly warned, even if Pfizer loses its second motion to dismiss, as sure as the sun will rise tomorrow, we can expect yet more gamesmanship and baseless motions by Pfizer designed to destroy jurisdiction and delay resolution of Apotex's Counterclaim. (D.I. 217-3, Pls.' br. Ex. C, Aug. 17 Tr. 7:9-20). The result will be a never-ending cycle of motions by Pfizer. This alone warrants denial of Pfizer's motion.

This Court ruled on June 30 that it has subject matter jurisdiction and, as explained in Apotex's brief in opposition to Pfizer's second motion to dismiss, absolutely nothing of significance has changed since the Court denied Pfizer's first motion to dismiss. (*See* D.I. 212, Def. Apotex's Br. in Opp'n to Pl. Pfizer's [Second] Mot. to Dismiss at 4-14). In short, enough is enough, and briefing over Apotex's summary judgment motions should proceed. Indeed, a stay on briefing would only encourage Pfizer to continue its subject matter jurisdiction manipulations indefinitely. Pfizer has provided no precedent or reason, much less a legitimate one, for denying Apotex its right to seek summary judgment.

Moreover, contrary to Pfizer's disingenuous assertions, this Court never intimated that "it makes no sense to proceed with briefing on Apotex's SJ Motions before deciding Pfizer's

pending motions challenging subject matter jurisdiction." (D.I. 217, Pls.' br. 7). Quite the contrary, in the portion of the August 17 transcript relied upon by Pfizer, the Court was addressing the order in which to decide Pfizer's second motion to dismiss, ***not*** whether to allow briefing on Apotex's summary judgment motions:

> THE COURT: . . . Okay, and then we have got a motion to dismiss and then we have got these summary judgment motions, so one issue is the sequencing of what's going to be more efficient here, ***and I can tell you my inclination, even if you did brief this, would be to resolve those other two first***. It just makes more sense that way.

(D.I. 217-3, Pls.' br. Ex. C, Aug. 17 Tr. 4:22 – 5:3 (emphasis added)). Again, Pfizer's outright mischaracterization entirely undermines the present motion. In fact, the Court made clear that it was inclined to proceed with briefing. (*Id*. at 8:7-9 ("THE COURT: . . . I think it's really going to be a burden on Pfizer to demonstrate that I shouldn't go ahead and let you brief this. . . .")).

C. Fact and Expert Discovery Are Not Necessary to Resolve Apotex's Summary Judgment Motions.

Pfizer asserts that "Courts and commentators alike agree that patent infringement is rarely amenable to summary disposition." (D.I. 217, Pls.' br. 7). This is nonsense. The Federal Circuit, which has exclusive jurisdiction over all patent appeals, has gone out of its way to "repeatedly emphasize[] that summary judgment is as appropriate in a patent case as in any other." *Avia Group Int'l, Inc. v. L.A. Gear Cal., Inc.*, 853 F.2d 1557, 1561 (Fed. Cir. 1988) (internal quotations omitted), *abrogated on other grounds by Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665 (Fed. Cir. 2008). "It is no longer debatable that the issues in a patent case are subject to summary judgment." *Id*.

Pfizer then suggests that "[s]ummary disposition is even less appropriate where, as here, the parties have not taken discovery, fact or expert, regarding the claims at issue," citing *Del Raso v. United States*, 244 F.3d 567, 570 (7th Cir. 2001), *Metropolitan Life Insurance Co. v. Bancorp Services, LLC*, 527 F.3d 1330, 1338 (Fed. Cir. 2008), and *Vivid Technologies, Inc. v.*

American Science & Engineering, Inc., 200 F.3d 795, 810 (Fed. Cir. 1999). (D.I. 217, Pls.' br. 8). Wrong again. To begin with, *Metropolitan Life* and *Vivid Technologies* are entirely distinguishable. There, unlike here, the respondents formally moved—and according to the Federal Circuit met their burden—under Rule 56(f). *Metro. Life*, 527 F.3d at 1337; *Vivid Techs.*, 200 F.3d at 807, 809-10. In stark contrast, Pfizer admittedly and purposefully did not move under Rule 56(f), or otherwise make the necessary particularized showing via affidavit. (D.I. 271, Pls.' br. 9). And Pfizer's trumpeting of dicta in *Del Raso* ignores well-settled Seventh Circuit law that "***Rule 56 does not require that discovery take place in all cases before summary judgment can be granted***." *Waterloo Furniture Components, Ltd. v. Haworth, Inc.*, 467 F.3d 641, 648 (7th Cir. 2006). Indeed, if anything is clear, it is that "[a] defendant may move for summary judgment ***at any time***," and "[t]he fact that discovery is not complete—***indeed, has not begun***—need not defeat [a summary judgment] motion." *Am. Nurses' Ass'n v. Illinois*, 783 F.2d 716, 729 (7th Cir. 1986) (emphasis added). Pfizer, of course, cites no law to the contrary—and for good reason, because there is none.

But, more importantly, Pfizer's argument entire argument assumes, without foundation, that fact or expert discovery is required to resolve Apotex's summary judgment motions—an entirely false assumption. Pfizer has already effectively conceded non-infringement of the '104 and '971 patents in the unilateral covenant-not-to-sue it issued to Apotex on July 21, 2010. (*See* D.I. 162-1, Pl. Pfizer's Br. in Supp. of its [Second] Mot. to Dismiss Ex. A, July 21, 2010 Covenant Not To Sue). The covenant states, in pertinent part, that:

> in reliance upon [Apotex's representations of non-infringement in its November 4, 2008 Paragraph IV notice letter, Pfizer] . . . hereby covenant[s] not to sue or otherwise hold Apotex liable for infringement under any claims of the ['104 and '971 patents] with respect to [the filing of Apotex's atorvastatin ANDA] or . . . [t]he manufacture, use, distribution, sale, offer for sale, or importation by, for or to Apotex of the products described in . . . [Apotex's atorvastatin ANDA] . . . .

(*Id*. at 1). In other words, Pfizer has clearly accepted the representations made in Apotex's November 4, 2008 Paragraph IV notice letter on Apotex's non-infringement of the '104 and '971 patents, including Apotex's constructions for claim terms of those patents, which are included in Apotex's '104 and '971 patent summary judgment motion brief. (*Compare* D.I. 161, Pls.' Second Mot. to Dismiss br. Ex. A, July 21, 2010 Covenant Not To Sue Ex. 1, Apotex's Nov. 4, 2008 Paragraph IV notice letter at Detailed Statement 17-30 and 47-59, *with* D.I. 178, Mem. of Law in Supp. of Apotex Inc. and Apotex Corp.'s Mot for Summ. J. of Non-Infringement of the '104 and '971 Patents). Therefore, there is absolutely no discovery—***none***—needed by Pfizer on Apotex's '104 and '971 patent summary judgment motion.[4] And thus, there is absolutely no reason to delay adjudication of that motion in Apotex's favor.

With respect to Apotex's '156 patent summary judgment motion, Apotex's ANDA and the DMF (Drug Master File) it references, which describes in detail the structural characteristics of the active pharmaceutical ingredient ("API") in Apotex's ANDA product, contain all of the information the parties and the Court need to resolve Apotex's '156 patent summary judgment motion. *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1248-50 (Fed. Cir. 2000) (Where "the specification in [the] ANDA defines [the] product in a way that directly addresses the question of infringement," the inquiry ends there and there is no recourse to evidence outside the ANDA). Therefore, absolutely no discovery is needed in connection with, and thus there is no reason to delay resolution of, Apotex's '156 patent summary judgment motion either.

[4] Indeed, it is telling that Pfizer does not even specifically request or identify any discovery that it needs with respect to Apotex's '104 and '971 patent summary judgment motion. (*See* D.I. 217, Pls.' br., generally). Moreover, to the extent that Pfizer contests non-infringement of the '104 and '971 patents in this case, it exposes the illusory nature of its covenant-not-to-sue and undercuts the entire premise of its second motion to dismiss (D.I. 161), which, as explained in Apotex's brief in opposition (D.I. 212), should be denied.

D. Pfizer Has Not Complied with the Requirements of Rule 56(f), but Even If It Had, its Motion Should Still Be Denied.

Pfizer admits that it has not formally moved under Rule 56(f), but nevertheless argues that "Rule [56(f)] counsels against" entertaining Apotex's summary judgment motions because Pfizer asserts, again without foundation or support, that it needs discovery on claim construction and infringement. (D.I. 217, Pls.' br. 9). But Seventh Circuit law is clear: "***a party's failure to file a Rule 56(f) affidavit warrants disregarding its asserted need for additional discovery***." *Intellect*, 2010 WL 3257924, at *2 (emphasis added) (citing *Chambers v. Am. Trans Air, Inc.*, 17 F.3d 998, 1002 (7th Cir. 1994)). As Judge Gottschall aptly in the *Intellect* case:

> THE COURT: Let me tell you the reality. Congress has passed something called the Civil Justice Reform Act. The effect of that Act on me is it means that all motions have to be decided within six months of a date, which takes a certain amount of study to figure out when it is, but it's a strange date.
>
> I can't have a motion filed that just sits. It's not possible. I would have to report it, I would have to explain why I'm behind on my docket, I would have to do all kinds of things I don't want to do. So what I have been asking people to do, the rule, Rule 56, gives you a way to tell me that the situation is not right for summary judgment, you file that, I deny it without prejudice, and we're done.
>
> Now, if everybody agrees that it's premature, the motion could be withdrawn. But ***I don't have any way to prevent anybody from filing a motion, and once a motion is filed, I have to proceed to get briefs and decide it***.

(Feb. 18, 2010 Tr. of Proceedings Before the Hon. Joan B. Gottschall 3:11 – 4:2, attached hereto as Ex. A). Judge Gottschall went on to reject the very same arguments made by Pfizer here precisely because the nonmovant (just like Pfizer here) "failed to comply with the required procedure to assert its need for additional discovery" under Rule 56(f). *Intellect*, 2010 WL 3257924, at *2. Moreover, a closer examination of the supposed "preview" that Pfizer provides for the alleged discovery it says is required confirms that, even if Pfizer had substantiated its claims for additional discovery with an affidavit (which it hasn't), Pfizer's motion must still be

denied because the discovery requested is irrelevant to Apotex's summary judgment motions.[5]

1. The Parties Previously Agreed—on Two Separate Occasions—that Claim Construction Is an Issue of Law for the Court to Decide and that No Discovery Is Necessary for Claim Construction in this Case.

Pfizer agreed—on two separate occasions—to forego *Markman* claim construction proceedings in this case in favor of any claim construction disputes being resolved during dispositive motions. (D.I. 50, Joint Rule 26(f) Report § M.3; D.I. 99, Revised Joint Rule 26(f) Report § P). Pfizer conveniently reverses course now that it wishes to delay resolution of Apotex's motions. Pfizer's arguments are without merit, both legally and factually.

To begin with, construction of patent claims is purely a legal function. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Accordingly, it is well-settled that "[d]isputes concerning the meaning of claims do not preclude summary judgment, because the resolution of those disputes is part of the process of claim interpretation, a question of law." *Phonometrics, Inc. v. N. Inc.*, 133 F.3d 1459, 1464 (Fed. Cir. 1998); *accord Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1387 (Fed. Cir. 1992) (same); *Wolverine World Wide, Inc. v. Nike, Inc.*, 38 F.3d 1192, 1196-97 (Fed. Cir. 1994) (same). Thus, Pfizer's argument that it requires discovery on this purely legal issue—that cannot preclude summary judgment anyway—simply doesn't pass the straight-face test.

Furthermore, the ***intrinsic*** evidence, including the claims, the specification, and the

[5] Pfizer curiously cites *Metropolitan Life* for the assertion that "a Rule 56(f) request should be granted without a strict showing of necessity and diligence where, as here, there has been no discovery." (D.I. 217, Pls.' br. 9 (citing *Metro. Life*, 527 F.3d at 1337)). But regional circuit law governs on Rule 56(f) issues, *Vivid Techs.*, 200 F.3d at 807, and the Seventh Circuit—which controls here—has not relaxed the necessary showing of necessity and diligence under Rule 56(f). *See Chambers*, 17 F.3d at 1002 (even where discovery is incomplete, "Rule 56(f) requires that [a nonmovant] explain why" it cannot present facts essential to justify opposition); *see also Daley v. Gorajec*, No. 1:06-cv-1493-JDT-WTL, 2007 WL 2286132, at *5 (S.D. Ind. Aug. 7, 2007) (where no discovery had taken place, a Rule 56(f) motion would be denied "[i]f [the nonmovant] fail[ed] to show how the discovery [sought] w[ould] help demonstrate the existence of a genuine issue of material fact.").

prosecution history—and ***not*** any ***extrinsic*** evidence that Pfizer may seek in discovery—is the primary source for determining claim meaning. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1315-18 (Fed. Cir. 2005) (en banc). This intrinsic evidence, of course, is already in Pfizer's possession. Anything else that Pfizer may seek, such as expert testimony, is necessarily ***extrinsic***. The Federal Circuit has made clear that such "extrinsic evidence in general [is] less reliable than the patent and its prosecution history in determining how to read claim terms for several reasons," including that "extrinsic evidence consisting of expert reports and testimony is generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Phillips*, 415 F.3d at 1318. Pfizer has made absolutely no showing—none—as to why extrinsic evidence is necessary to construe claim terms of the '104, '156, and '971 patents.[6] Nor could it, especially since such evidence can't be used to preclude summary judgment in any event.

Moreover, Pfizer notably does not point to a single claim term in the '104 and '971 patents that might require construction, much less discovery. And for those terms in the '156 patent that Pfizer says it disagrees with Apotex's constructions, Pfizer does not explain why, let alone why discovery is somehow necessary (D.I. 217, Pls.' br. 10-11), or why the intrinsic record for its own patents, on which the Federal Circuit relies, is insufficient. This, too, is fatal to Pfizer's motion.

[6] Pfizer quotes language from the "additional views" expressed by Judges Rader and Plager in *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298 (Fed. Cir. 1999), ***not*** from the opinion of the court, in support of its assertion that expert testimony is necessary in this case to provide the Court with "helpful context" so that the Court can ascertain "what one skilled in the art would consider to be the ordinary meaning" of disputed claim terms. (D.I. 217, Pls.' br. 10). But the views expressed on expert testimony by the Federal Circuit en banc in *Phillips* supersedes the "additional views" relied upon by Pfizer from the *Pitney Bowes* case. Moreover, the *Phillips* court cited with approval its previous decision in *V-Formation, Inc. v. Benetton Group, SpA*, 401 F.3d 1307 (Fed. Cir. 2005), which pointed out that the intrinsic evidence "usually provides the technological and temporal context to enable the court to ascertain the meaning of the claim to one of ordinary skill in the art at the same time of the invention." *V-Formation*, 401 F.3d at 1310; *see also Phillips*, 415 F.3d at 1313.

In a desperate attempt to push its claim construction argument further, Pfizer points to language from the Local Patent Rule 1.1, while in the same breath conceding that this case is not subject to this District's Local Patent Rules. Pfizer also points to this Court's "Standing Order for Claim Construction," while utterly failing to mention that it specifically requested from this Court (twice) that it be exempted from the requirements of that order (D.I. 50, Joint Rule 26(f) Report § M.3; D.I. 99, Revised Joint Rule 26(f) Report § P). (D.I. 217, Pls.' br. 11). And once again, Pfizer completely fails to explain why the intrinsic evidence it has before it ***on its own patents*** is not enough to define the claim terms of those patents. Indeed, as recently as July 26, 2010, Pfizer again proposed a schedule that did ***not*** include a *Markman* proceeding. (*See* D.I. 165, Status Report by Pls.' Pfizer 4). If claim construction were truly as important as Pfizer makes it out to be now, why—particularly after it asserted the '156 patent against Apotex—did it not include *Markman* proceedings in its proposed schedule? The answer is simple and straightforward—because Pfizer doesn't actually need or want claim construction proceedings, but rather just wants delay for the sake of delay.

2. No Discovery Is Required on Non-Infringement.

For at least the reasons explained in Section III.C., *supra*, no discovery on non-infringement is needed in connection with Apotex's summary judgment motions because Pfizer has conceded non-infringement of the '104 and '971 patents, and because all of the information the parties and the Court need to assess non-infringement of the '156 patent is contained within Apotex's ANDA and DMF, which are already in Pfizer's possession. *See Bayer*, 212 F.3d at 1248-50. Pfizer nonetheless argues, again without any support, that *Bayer* is inapposite because Apotex's "ANDA specification does not preclude the presence of Pfizer's patented crystalline forms[.]" (D.I. 217, Pls.' br. 12).

As an initial matter, this issue goes to the merits, and is reason to decide the motion, not

delay it. Pfizer shouldn't be permitted to delay Apotex's motion merely by arguing that it disagrees with the merits of that very same motion. Rather, Pfizer should just respond to the motion if it disagrees with anything in it.

But just as importantly, Pfizer is profoundly mistaken. In reality, Apotex's ANDA (and the DMF it references) does contain information that conclusively shows that Apotex's ANDA product does not, and will not, contain any of the forms claimed in the '156 patent, and this information is included in Apotex's '156 patent summary judgment papers. Specifically, Apotex's '156 patent summary judgment motion includes spectra for powder x-ray diffraction testing performed on Apotex's pre-formulated API and—contrary to Pfizer's assertion—for x-ray powder diffraction testing performed on Apotex's formulated product under stress conditions to show that absolutely no conversion takes place. (*See* D.I. 202-3, 202-5, Decl. of Andrew M. Alul, Esq. in Supp. of Apotex's Mot. for Summ. J. on Non-Infringement of the '156 patent ("8/6/10 Alul Decl.") Exs. F and N). Pfizer goes on to criticize the nuclear magnetic resonance ("NMR") data provided in Apotex's summary judgment papers as solution, and not solid-state NMR data, but Pfizer fails to explain—with the specificity required by Rule 56(f)—why the data is insufficient to show that Apotex's ANDA product does not contain the claimed forms.[7] Moreover, the solid-state characterization test information in Apotex's ANDA and '156 patent summary judgment papers does identify how the tests were performed. (*See id.*)

In sum, Pfizer has failed to comply with the required procedures of Rule 56(f) in explaining why it needs additional fact and expert discovery to properly respond to Apotex's '156 patent summary judgment motion. Moreover, Pfizer does not even point to what type of

[7] Moreover, even assuming, *arguendo*, that Pfizer is correct in its characterization of Apotex's NMR data, Apotex has an independent basis for non-infringement of each '156 patent claim that recites NMR spectral features—specifically, that Apotex's ANDA product does not include any anhydrous or hydrated forms of atorvastatin, confirmed by numerous characterization techniques, data for which is included in Apotex's ANDA. (*See* D.I. 202-3, 8/6/10 Alul Decl. Ex. N). Pfizer utterly fails to address this.

discovery it needs in connection with Apotex's '104 and '971 patents. In fact, Apotex's ANDA contains *all* the information needed to assess infringement and Pfizer should be required to respond to Apotex's summary judgment motions in accordance with FED. R. CIV. P. 56.

E. Summary Judgment Would Promote Judicial Economy and There Is No Restriction on Early Summary Judgment.

Contrary to Pfizer's arguments, resolution of Apotex's summary judgment motions would promote judicial economy because, if granted, Apotex's summary judgment motions would dispose of numerous claims and defenses in the lawsuit, drastically narrowing issues to be tried in this case. *See Intellect*, 2010 WL 3257924, at *3 (proceeding with summary judgment on less than all of the patents-in-suit promotes, rather than undermines, judicial economy). Moreover, Pfizer's sequence argument (D.I. 217, Pls.' br. 14-15) is entirely without merit, as Apotex never agreed to a bar on the early filing of summary judgment motions, something encouraged under the Federal Rules. *See* FED. R. CIV. P. 56(c)(1)(A) ("[A] party may move for summary judgment ***at any time*** . . . ." (emphasis added)).

IV. CONCLUSION.

For the foregoing reasons, Pfizer's Motion to deny or stay briefing on Apotex's summary judgment motions should be denied.

Dated: September 24, 2010.

Respectfully submitted,

APOTEX INC. AND APOTEX CORP.

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CERTIFICATE OF SERVICE

I, Andrew M. Alul, an attorney, hereby certify that on this 24th day of September, 2010, a true and correct copy of the foregoing DEFENDANT APOTEX'S BRIEF IN OPPOSITION TO PLAINTIFF PFIZER'S MOTION TO DENY APOTEX'S MOTIONS FOR SUMMARY JUDGEMENT OR, ALTERNATIVELY, TO STAY BRIEFING [DKT. ITEM NO. 216] was filed with the Clerk of the Court using the Electronic Case Filing (ECF) system which will send notification of such filing via electronic mail to all counsel of record.

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